# Dialysis Medical Solutions, LLC

**Dialysis Concentrate for Hemodialysis (Powder) "Traditional" 510(k) Premarket Notification**

APR 0 3 2014

## 510(K) SUMMARY UNDER 21 CFR 807.92

This 510(k) summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content in this 510(k) summary has been provided in conformance with 21 CFR Part 807.92.

## A. Submitter's Information

| | |
|---|---|
| (1) Name: | McNees, Wallace & Nurick LLC |
| (2) Address: | 21 East State St., Suite 1700, Columbus, OH 43215 USA |
| (3) Phone: | 614-719-2858 |
| (4) Fax: | 614-469-4653 |
| (5) Contact Person: | (Mr.) Courtney J. Miller, J.D., LL.M. |
| (6) Preparation Date: | April 18, 2013 |
| (7) Revision Date: | September 24, 2013 |

***On Behalf of Applicant Entity (owner of 510(k))***

| | |
|---|---|
| (1) Applicant Name: | Dialysis Medical Solutions, LLC |
| (2) Applicant Address: | 509 Fishing Creek Rd., Lewisberry, PA 17339 USA |
| (3) Applicant Phone: | 717-938-8391 |
| (4) Applicant Fax: | 717-938-3957 |
| (5) Establishment Reg. No: | 1528807 |

## B. Device Name

| | |
|---|---|
| (1) Trade Name: | MedicaLyte® Bicarbonate Powder |
| (2) Common Name: | Dialysis Concentrate for Hemodialysis (Powder) (Sodium Bicarbonate or Sodium Bicarbonate Chloride) |
| (3) Classification: | Class II, per 21 CFR 876.5820 (Dialysate Concentrate for Hemodialysis (liquid or powder)) |
| (4) Product Code: | KPO: Gastroenterology/Urology |

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### C. Legally Marketed Predicate Device

Rockwell Medical Supply RenalPure® Powder Bicarbonate for Hemodialysis (K954527)

Medivator Inc. Renasol® and Centrisol® Bicarbonate Concentrate Powder (K843963)

Di-Chem, Inc. Hemo-Lyte Dry Sodium Bicarbonate-Chloride Concentrate and Dry Sodium Bicarbonate Concentrate (K012328)

### D. Device Description

The MedicaLyte® Bicarbonate Powder devices for bicarbonate dialysis are comprised of USP grade sodium bicarbonate for 35X (DB-209, DB-210 and DB-211) and 45X (DB-206, DB-207 and DB-208) proportioning dialysis machines and USP grade sodium bicarbonate and USP grade sodium chloride for 36.83X proportioning dialysis machines (DB-203, DB-204 and DB-205). These products may be used in conventional, commercially available hemodialysis machines or monitors as one of the necessary components of three-component hemodialysis solution. The hemodialysis concentrate solutions presented in this 510(k) premarket notification are intended to be used in three-stream hemodialysis machines in which an acid concentrate is proportioned into one stream, a bicarbonate solution is prepared from the bicarbonate powder is proportioned into a second stream, and water is proportioned into the third stream of the hemodialysis machine proportioning system. These three streams are then mixed by the hemodialysis machine to prepare the final proportioned hemodialysis solution. The final hemodialysis solution is separated from the patient's blood by semi-permeable membranes which permit the passage of waste products and toxins contained in the patient's blood circulating through the hemodializer, and such waste products and toxins pass through the semi-permeable membranes into the hemodialysis solution and exit the hemodializer with the hemodialysis solution. By such treatment, waste products and toxins are removed from the patient's blood during acute and end-stage renal failure.

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### E. Intended Use

For DB-203; DB-204; DB-205:

This product is formulated to be used in conjunction with MedicaPure® liquid acid concentrate or equivalent in a 36.83x three-stream artificial kidney (hemodialysis) machine for use in treating a patient in need of hemodialysis.

-or-

For DB-206; DB-207; DB-208:

This product is formulated to be used in conjunction with MedicaPure® liquid acid concentrate or equivalent in a 45x three-stream artificial kidney (hemodialysis) machine for use in treating a patient in need of hemodialysis.

-or-

For DB-209; DB-210; DB-211:

This product is formulated to be used in conjunction with MedicaPure® liquid acid concentrate or equivalent in a 35x three-stream artificial kidney (hemodialysis) machine for use in treating a patient in need of hemodialysis.

These indication statements are essentially equivalent to the indication statement for the predicate devices.

### F. Technological Characteristics:

Comparing the proposed MedicaLyte® Bicarbonate Powder devices to the RenalPure® Powder Bicarbonate predicate devices, the devices utilize the chemical compositions and produce the same bicarbonate solutions for hemodialysis (as described in Table 1). There are no significant differences, and therefore a finding of substantial equivalence is appropriate.

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**TABLE 1. Performance Comparison Table (Bicarbonate Stream Dialysate Generated from Concentrate According to Label Directions)***

| Device | Volume | Component | Yield | Predicate Device |
|---|---|---|---|---|
| **DB-203: MedicaLyte® Bicarbonate Powder (36.83X)** | 2.5 Gallons | Sodium | 59 mEq/L | **RB Series RenalPure® Powder Bicarbonate 2.5 Gallon Packet** |
| | | Bicarbonate | 39 mEq/L | |
| | | Chloride | 20 mEq/L | |
| **DB-204: MedicaLyte® Bicarbonate Powder (36.83X)** | 15 Gallons | Sodium | 59 mEq/L | **RB Series RenalPure® Powder Bicarbonate 15 Gallon Packet** |
| | | Bicarbonate | 39 mEq/L | |
| | | Chloride | 20 mEq/L | |
| **DB-205: MedicaLyte® Bicarbonate Powder (36.83X)** | 25 Gallons | Sodium | 59 mEq/L | **RB Series RenalPure® Powder Bicarbonate 25 Gallon Packet** |
| | | Bicarbonate | 39 mEq/L | |
| | | Chloride | 20 mEq/L | |
| **DB-206: MedicaLyte® Bicarbonate Powder (45X)** | 2.1 Gallons | Sodium | 37 mEq/L | **CB Series RenalPure® Powder Bicarbonate 2.1 Gallon Packet** |
| | | Bicarbonate | 37 mEq/L | |
| **DB-207: MedicaLyte® Bicarbonate Powder (45X)** | 15 Gallons | Sodium | 37 mEq/L | **CB Series RenalPure® Powder Bicarbonate 15 Gallon Packet** |
| | | Bicarbonate | 37 mEq/L | |
| **DB-208: MedicaLyte® Bicarbonate Powder (45X)** | 25 Gallons | Sodium | 37 mEq/L | **CB Series RenalPure® Powder Bicarbonate 25 Gallon Packet** |
| | | Bicarbonate | 37 mEq/L | |
| **DB-209: MedicaLyte® Bicarbonate Powder (35X)** | 2.5 Gallons | Sodium | 35 mEq/L | **FB Series RenalPure® Powder Bicarbonate 2.5 Gallon Packet** |
| | | Bicarbonate | 35 mEq/L | |
| **DB-210: MedicaLyte® Bicarbonate Powder (35X)** | 15 Gallons | Sodium | 35 mEq/L | **FB Series RenalPure® Powder Bicarbonate 15 Gallon Packet** |
| | | Bicarbonate | 35 mEq/L | |
| **DB-211: MedicaLyte® Bicarbonate Powder (35X)** | 25 Gallons | Sodium | 35 mEq/L | **FB Series RenalPure® Powder Bicarbonate 25 Gallon Packet** |
| | | Bicarbonate | 35 mEq/L | |

*The Volume, Component and Yield columns apply equally to the Device and Predicate Device.

Comparing the relevant proposed MedicaLyte® Bicarbonate Powder devices to the Renasol® and Centrisol® Bicarbonate Concentrate Powder predicate devices, the devices utilize the chemical compositions and produce the same bicarbonate solutions for hemodialysis (as described in Table 2). There are no significant differences, and therefore a finding of substantial equivalence is appropriate.

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**TABLE 2. Performance Comparison Table (Bicarbonate Stream Dialysate Generated from Concentrate According to Label Directions)***

| Device | Volume | Component | Yield | Predicate Device |
|---|---|---|---|---|
| **DB-203: MedicaLyte® Bicarbonate Powder (36.83X)** | 2.5 Gallons | Sodium | 59 mEq/L | **BC-1 Renasol® Bicarbonate Concentrate Powder** |
| | | Bicarbonate | 39 mEq/L | |
| | | Chloride | 20 mEq/L | |
| **DB-204: MedicaLyte® Bicarbonate Powder (36.83X)** | 15 Gallons | Sodium | 59 mEq/L | **BC-1-15 Renasol® Bicarbonate Concentrate Powder** |
| | | Bicarbonate | 39 mEq/L | |
| | | Chloride | 20 mEq/L | |
| **DB-205: MedicaLyte® Bicarbonate Powder (36.83X)** | 25 Gallons | Sodium | 59 mEq/L | **BC-1-25 Renasol® Bicarbonate Concentrate Powder** |
| | | Bicarbonate | 39 mEq/L | |
| | | Chloride | 20 mEq/L | |
| **DB-206: MedicaLyte® Bicarbonate Powder (45X)** | 2.1 Gallons | Sodium | 37 mEq/L | **MB-330 Centrisol® Bicarbonate Concentrate Powder** |
| | | Bicarbonate | 37 mEq/L | |
| **DB-207: MedicaLyte® Bicarbonate Powder (45X)** | 15 Gallons | Sodium | 37 mEq/L | **MB-330-15 Centrisol® Bicarbonate Concentrate Powder** |
| | | Bicarbonate | 37 mEq/L | |
| **DB-208: MedicaLyte® Bicarbonate Powder (45X)** | 25 Gallons | Sodium | 37 mEq/L | **MB-330-25 Centrisol® Bicarbonate Concentrate Powder** |
| | | Bicarbonate | 37 mEq/L | |

*The Volume, Component and Yield columns apply equally to the Device and Predicate Device, except that MB-330 lists a total volume of 2.11 Gallons rather than 2.1 Gallons due to listing an additional significant figure in the conversion from metric to English standard units.

Comparing the relevant proposed MedicaLyte® Bicarbonate Powder devices to the Hemo-Lyte Dry Sodium Bicarbonate-Chloride Concentrate and Dry Sodium Bicarbonate Concentrate predicate devices, the devices utilize the chemical compositions and produce the same bicarbonate solutions for hemodialysis (as described in Table 3). There are no significant differences, and therefore a finding of substantial equivalence is appropriate.

**Dialysis Medical Solutions, LLC**
**Dialysis Concentrate for Hemodialysis (Powder) "Traditional" 510(k) Premarket Notification**

**510(K) SUMMARY UNDER 21 CFR 807.92**

**TABLE 3. Performance Comparison Table (Bicarbonate Stream Dialysate Generated from Concentrate According to Label Directions)***

| Device | Volume | Component | Yield | Predicate Device |
|---|---|---|---|---|
| **DB-203: MedicaLyte® Bicarbonate Powder (36.83X)** | 2.5 Gallons | Sodium | 59 mEq/L | **DB-1-2.5 Hemo-Lyte Dry Sodium Bicarbonate-Chloride Concentrate** |
| | | Bicarbonate | 39 mEq/L | |
| | | Chloride | 20 mEq/L | |
| **DB-204: MedicaLyte® Bicarbonate Powder (36.83X)** | 15 Gallons | Sodium | 59 mEq/L | **DB-1-15 Hemo-Lyte Dry Sodium Bicarbonate-Chloride Concentrate** |
| | | Bicarbonate | 39 mEq/L | |
| | | Chloride | 20 mEq/L | |
| **DB-205: MedicaLyte® Bicarbonate Powder (36.83X)** | 25 Gallons | Sodium | 59 mEq/L | **DB-1-25 Hemo-Lyte Dry Sodium Bicarbonate-Chloride Concentrate** |
| | | Bicarbonate | 39 mEq/L | |
| | | Chloride | 20 mEq/L | |
| **DB-206: MedicaLyte® Bicarbonate Powder (45X)** | 2.1 Gallons | Sodium | 37 mEq/L | **DB-2-2.1 Hemo-Lyte Dry Sodium Bicarbonate Concentrate** |
| | | Bicarbonate | 37 mEq/L | |
| **DB-207: MedicaLyte® Bicarbonate Powder (45X)** | 15 Gallons | Sodium | 37 mEq/L | **DB-2-15 Hemo-Lyte Dry Sodium Bicarbonate Concentrate** |
| | | Bicarbonate | 37 mEq/L | |
| **DB-208: MedicaLyte® Bicarbonate Powder (45X)** | 25 Gallons | Sodium | 37 mEq/L | **DB-2-25 Hemo-Lyte Dry Sodium Bicarbonate Concentrate** |
| | | Bicarbonate | 37 mEq/L | |

*The Volume, Component and Yield columns apply equally to the Device and Predicate Device.

## G. Conclusion

The MedicaLyte® Bicarbonate Powder devices are believed to be substantially equivalent in design, materials, and intended use to the commercially available Rockwell Medical Supply RenalPure® Powder Bicarbonate (K954527) predicate devices, the Medivator Inc. Renasol® and Centrisol® Bicarbonate Concentrate Powder (K843963) predicate devices, and the Di-Chem, Inc. Hemo-Lyte Dry Sodium Bicarbonate-Chloride Concentrate and Dry Sodium Bicarbonate Concentrate (K012328) predicate devices, and are therefore expected to be as safe, as effective, and perform as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 3, 2014

Dialysis Medical Solutions, LLC
% David M. Marcus, J.D., Ph.D.
Associate / Registered Patent Attorney
McNees Wallace & Nurick LLC
21 East State Street, Suite 1700
Columbus, OH 43215

Re: K131202
Trade/Device Name: MedicaLyte® Bicarbonate Powder
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: KPO
Dated: February 24, 2014
Received: February 25, 2014

Dear David M. Marcus,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Dialysis Medical Solutions, LLC

**Dialysis Concentrate for Hemodialysis (Powder) "Traditional" 510(k) Premarket Notification**

## INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K131202

Device Name: MedicaLyte® Bicarbonate Powder

Indications for Use:

For DB-203; DB-204; DB-205:

This product is formulated to be used in conjunction with MedicaPure® liquid acid concentrate or equivalent in a 36.83x three-stream artificial kidney (hemodialysis) machine for use in treating a patient in need of hemodialysis.

-or-

For DB-206; DB-207; DB-208:

This product is formulated to be used in conjunction with MedicaPure® liquid acid concentrate or equivalent in a 45x three-stream artificial kidney (hemodialysis) machine for use in treating a patient in need of hemodialysis.

-or-

For DB-209; DB-210; DB-211:

This product is formulated to be used in conjunction with MedicaPure® liquid acid concentrate or equivalent in a 35x three-stream artificial kidney (hemodialysis) machine for use in treating a patient in need of hemodialysis.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Benjamin R. Fisher -S FDA
2014.04.03 15:05:38 -04'00'

Concurrence of CDRH, Office of Device Evaluation (ODE)